

REMARKS

The present invention relates to an inline process for controlling and monitoring a nitration process. In this process, the reaction mixture containing the nitration product and unused reactants and by-products separates into an organic phase containing the nitrated product and an acid phase containing the unused nitric acid and other unused reactants and by-products. It is the composition of the acid phase containing unused nitric acid and other unused reactants and by-products which is determined spectrometrically. The data from this determination is then relayed to a process control system in order to monitor and control the production process.

Claims 1-24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hallinan et al (U.S. Patent 6,103,934) in view of NPL, David Firth Reference "Nitration Reactions in the manufacture of pharmaceutical intermediates" (hereinafter referred to as "Firth"). Applicants respectfully traverse this rejection.

Hallinan et al discloses a process for the production of acetic acid and a method for controlling that process. In the disclosed method, reaction mixture from which the desired acid product has not been removed that also contains unused reactants, catalyst and by-product is analyzed. Such analysis before the desired product, i.e., acetic acid is removed from that mixture in the flash tank can not therefore reflect any loss of reactant or catalyst during separation of the acetic acid product. The adjustment of the concentration of methyl iodide, water, and active catalyst based on measurement of the product-containing reaction mixture in an infrared analyzer may therefore be less than optimum.

Hallinan et al does not teach or suggest infrared analysis of an acid phase of a nitration reaction mixture as is required in Applicants' claimed invention. Nor does Hallinan et al teach or suggest infrared analysis of the reaction mixture after the product has been removed from the reaction mixture as is required in Applicants' claimed invention.

It is stated in the Office Action that the teachings of Firth would motivate one skilled in the art to adapt the process disclosed by Hallinan et al to a nitration process of the type disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

Applicants maintain that (1) that one skilled in the art would not consider it obvious to combine the teachings of the cited references; and (2) even if one skilled in the art were to consider it "obvious to try" to combine the teachings of Hallinan et al and Firth, that skilled artisan would not "arrive at" their claimed invention.

More specifically, Firth teaches that automated monitoring techniques may be used to improve a process such as the continuous process for producing nitroglycerine disclosed therein by the use of control loops. Firth does not teach or suggest that any particular automated monitoring technique would be any more advantageous than another. That is, there is no teaching in Firth which would lead one skilled in the art to select the monitoring technique disclosed by Hallinan et al from the many other known monitoring techniques known to those skilled in the art.

Further, Hallinan et al teaches analysis of a reaction mixture from which the product has not yet been removed. Firth is silent with respect to the point at which analysis should be conducted. Combination of the teachings of the cited references will therefore result in a process in which a reaction mixture from which the product has not yet been removed is analyzed. Any loss of reactant or catalyst during separation of the desired product from the reaction mixture will not therefore be reflected in the infrared analysis conducted on that reaction mixture prior to separation in accordance with the teachings of Hallinan et al.

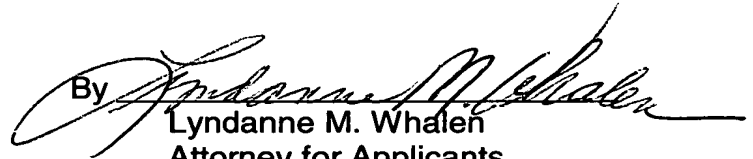
Applicants' process does not, however, require analysis of the organic phase containing the desired nitration product. Applicants' process requires analysis of the acid phase, i.e., the phase from which nitration product has been separated. Any loss of material in the course of separation of the nitration product from the reaction mixture will therefore be reflected in the analysis required by Applicants' claimed invention.

In short, neither Hallinan et al nor Firth teaches or suggests analysis of a reaction mixture after product separation in the manner required in Applicants' invention. Since this difference in the point at which the analysis is conducted obviously affects the accuracy of the analysis, the combined teachings of Hallinan et al and Firth do not render Applicants' claimed invention obvious.

Withdrawal of this rejection is therefore requested.

In view of the above remarks, reconsideration and allowance of Claims 1-24 are respectfully requested.

Respectfully submitted,

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